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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/004,686	12/05/2001	Yinghong Yu	13569.0019US01	7614

23552 7590 08/25/2004

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EXAMINER

SCHAETZLE, KENNEDY

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 08/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/004,686	Applicant(s) YU ET AL.	
	Examiner Kennedy Schaetzle	Art Unit 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 June 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) 1-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22-28 and 32-38 is/are rejected.
- 7) ☒ Claim(s) 29-31, 39 and 40 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 December 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>3/21/02</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of the invention of Group II (claims 22-40) in the reply filed on June 25, 2004 is acknowledged.

Claim Rejections - 35 USC § 101

2. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

3. Claims 23 and 33 are rejected under 35 U.S.C. 101 because the phrase "...sensing means is disposed within a vein..." implies that the vein --non-statutory subject matter-- is being claimed in combination with the sensing means. The examiner suggests to simply amend the claim to read that the sensing means is *adapted to be* disposed within a vein, in order to obviate the rejection under §101.

Claim Rejections - 35 USC § 102/103

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 22-25, 27, 28, 32-35, 37 and 38 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Cunningham (Pat. No. 6,077,236).

Regarding claim 22, Cunningham discloses a cardiac motion sensor unit comprising an acceleration sensing device 2 that generates a signal representative of movement of a cardiac wall, a conductor device with an elongated insulator body (insulated wires 7 and 8 as discussed in col. 6, lines 47-50) that transmit the signal to an electronic device, and a connector device (generally shown by the switching arrangement with positions 13 and 113 as shown in Fig. 15). The examiner also notes that, while not explicitly shown, the pacing/sensing lead must have some form of traditional connector device (commonly a connector pin arrangement) if it is to connect to the electronic device 9. In any event, the switching arrangement is considered to constitute a connector device.

Regarding the term "molded into," the examiner considers such a term to relate to a product-by-process limitation. Such claims are only limited by the structure implied by the steps, and not the step(s) itself. The claimed product appears to be the same or similar to that of the Cunningham device since both products would contain an insulating layer over the conductor. Furthermore, it would not appear to make any difference as to how the insulative material was applied from an operational standpoint. Clearly an insulator body is required to prevent signal interference and shorting of signals between conductors. How such a body is constructed with respect to a conductor is of little consequence to this issue. A related comment applies to claim 25.

Regarding claim 23, limitations relating to the position of structure within the body fail to saliently distinguish over the apparatus of Cunningham which is considered to be capable of such placement simply depending on the size of the vein and the species under treatment.

The limitations set forth in claims 24 and 27 are clearly shown.

Regarding claim 28, note col. 7, lines 25-31.

With reference to claims 32-35, 37 and 38, note the comments made in the rejection of similarly worded claims above.

Claim Rejections - 35 USC § 103

7. Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cunningham (Pat. No. 6,077,236).

Cunningham does not discuss the type of material used to provide the insulation on the conductor device. The examiner takes Official Notice that polymers are well-known stable, biocompatible insulators and find common use in a wide variety of applications including medical device applications for maintaining electrical isolation of conductors.

Allowable Subject Matter

8. Claims 29-31, 39 and 40 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

There is no teaching in the prior art of record for modifying the lead of Cunningham to contain a second concentric cylindrical lead with conductive means for sensing cardiac electrical activity.

Conclusion

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

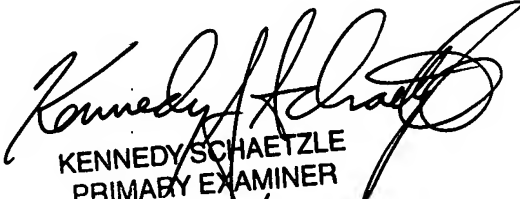
10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kennedy Schaetzle whose telephone number is 703 308-2211. The examiner can normally be reached on 9:30 -6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 703 308-0851. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 3762

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KJS
August 21, 2004


KENNEDY SCHAETZLE
PRIMARY EXAMINER
8/21/04